UNITED STATES ENVIRONMENTAL PROTECTION AGENCY Washington, D.C. 20460



OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Antimicrobial Division

June 30, 2016

DP BARCODE: 432640

MRID(s): 497762-02

SUBJECT: Bioguard MSA Algicide

REG. NO. OR FILE SYMBOL: 5185-382

DOCUMENT TYPE: Acute Toxicity Review

Manufacturing-use [] OR End-use Product [X]

INGREDIENTS:

PC Code(s) CAS Number(s) Active Ingredient(s):

024403 82027-59-6 Copper Triethanolamine Complex

069105 68424-85-1 n-Alkyl dimethyl ethylbenzyl ammonium chloride (C14

50%, C12 40%, C16 10%)

TEST LAB: Product Safety Lab

SUBMITTER: Bio-Lab, Inc.

GUIDELINE(s): 870.1300

COMMODITIES: N/A

REVIEWER: Boris S. Yurchak ORGANIZATION: AD/PSB/CTT

APPROVER: Karen P. Hicks APPROVED DATE: 7 / / /2016

COMMENT: This product is for non-food use

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June 30, 2016

MEMORANDUM

SUBJECT: Acute Toxicity Review for EPA Reg. No. 5185-382

Product Name: Bioguard MSA Algicide

DP Barcode: 432640

TO: Rose Kyprianou / Timothy Young

Regulatory Management Branch II Antimicrobials Division (7510P)

FROM: Boris S. Yurchak, Chemist

Product Science Branch, CT Team Antimicrobials Division (7510P)

THRU: Karen P. Hicks, CT Team Leader

Product Science Branch

Antimicrobials Division (7510P)

APPLICANT: Bio-Lab, Inc

Action code: (A676) Product Reregistration Decision

Due out date: July 1, 2016

PRODUCT FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Copper Triethanolamine Complex	23.6
n-Alkyl dimethyl ethylbenzyl ammonium chloride (C14 50%, C12 40%, C16 10%)	2.5
Other Ingredient(s)	<u>73.9</u>
TOTAL	100.0

BACKGROUND:

The registrant is submitting the acute inhalation study (81-3) in MRID 497762-02 to support the reregistration of the subject product, Bioguard MSA Algicide, EPA Reg. No. **5185-382**. The study was conducted by Product Safety Labs. The test material used in the studies was the subject product. The product is used for controlling algae in swimming pools.

The data package included:

- 1. Basic Confidential Statements of Formula (CSF), dated 03/08/2010.
- 2. Accepted label, dated 06/27/2016.

FINDINGS:

- 1. The acute inhalation study (81-3) is acceptable.
- 2. The acute toxicity profile for EPA Reg. No. 5185-382 is currently:

GRN	Study	MRID	Toxicity Category	Status
81-1	Acute Oral Toxicity	No data		Data gap
81-2	Acute Dermal Toxicity	No data		Data gap
81-3	Acute Inhalation Toxicity	49776202	II	Acceptable
81-4	Primary Eye Irritation	No data		Data gap
81-5	Primary Dermal Irritation	No data		Data gap
81-6	Dermal Sensitization	No data		Data gap

CONCLUSION:

The acute inhalation toxicity requirements have been satisfied for the subject product EPA Reg. No. 5185-382.

The precaution label statement might be composed after reviewing of data pertained to all endpoints of product toxicity.

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (OCSPP 870.1300)

Product Manager: J. Chao / 33 Reviewer: B. Yurchak

Study Completion Date: 11/17/2015

Report No.: 41772

Testing Laboratory: Product Safety Labs

Author: Jennifer Durando, BS

MRID No.: 49776202

Quality Assurance (40 CFR §160): Included

Test Material: BioGuard MSA Algicide II **Concentration**: Gravimetric – 0.062 mg/L

Nominal - 2.748 mg/L

Chamber Type: Nose-only

Species: Rat, Sprague-Dawley **Sex**: 5 Males and 5 Females

Age: 9-10 weeks

Weight: Males 295-322 g, Females 192-224 g

Source: SAGE Labs

Summary:

1. Estimated LC₅₀: > 0.062 mg/L

2. Average MMAD: 2.21 µm; Average GSD: 2.41

Toxicity Category: II
Classification: Acceptable

Deviations from Guideline 870.1300 and other comments: None

Results:

Male and female rats were exposed nose-only to the test atmosphere for 4 hours at 0.062 mg/L. All animals survived exposure to the test substance and gained body weight during the study. Clinical abnormalities observed irregular respiration. All animals recovered by Day 2 and appeared active and healthy for the duration of the study. No gross abnormalities were noted for any of the animals when necropsied at the conclusion of the 14-day observation period. The median lethal was estimated to be > 0.062 mg/L in male and female rats.

Reported Mortality

Exposure	Number of deaths / number tested		
Concentration (mg/L)	Males	Females	Combined
0.062	0/5	0/5	0 / 10

Chamber Atmosphere

Exposure Concentration (mg/L)	Mean MMAD (μm)	Mean GSD	
0.062	2.21	2.41	

Chamber Environment

Exposure Level (mg/L)	0.062
Chamber Volume (L)	28
Total Airflow Rate (Lpm)	25
Temperature (°C)	20-21
Relative Humidity (%)	40-42